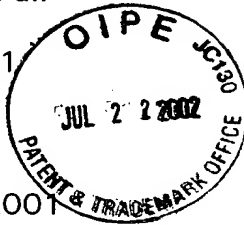


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Banerjee *et al.*
Serial No.: 09/887,281
Confirmation No.: 6268
Filed: June 22, 2001
For: BRONCHODILATING COMPOSITIONS
AND METHODS
Art Unit: 1614
Examiner: Weddington, K.



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#10

PETITION UNDER 37 C.F.R. §1.144
PETITION FROM REQUIREMENT FOR RESTRICTION

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U.S. Patent and Trademark Office
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Dear Sir:

Applicant hereby petitions under 37 C.F.R. §1.144 from a Restriction Requirement in the above-captioned application. Applicant requests removal of the Requirement as between Group I and claims 65-67, 92 and 93 of Group II, and as between Group I and claims 71-73 of Group IV. In view of Applicant's previous election of Group I, Applicant respectfully requests that Group I, claims 65-67, 92 and 93 of Group II, and claims 71-73 of Group IV, be combined for examination in this application. It is respectfully submitted that Group I is related to each of Groups II (in part, claims 65-67, 92 and 93) and IV (in part, claims 71-73) as a subcombination/combination for which a showing of two-way distinctness is required.

STATEMENT OF FACTS

The Requirement was set forth in a written Restriction Requirement, mailed January 30, 2002. The Requirement set forth four (4) Groups for

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election. Applicant elected, with traverse, Group I, and requested reconsideration of the Requirement as between Group I and claims 65-67, 92 and 93 of Group II, and as between Group I and claims 71-73 of Group IV, in the Election and Preliminary Amendment, mailed February 28, 2002.

Applicant's arguments were not deemed persuasive. The Requirement was made final in an Office Action, mailed May 22, 2002.

ARGUMENT

Applicant respectfully petitions for reconsideration and removal of the Requirement as between Group I and claims 65-67, 92 and 93 of Group II, and as between Group I and claims 71-73 of Group IV, in view of the following remarks.

The Office Action, mailed May 22, 2002, urged that the Restriction Requirement is based on the previous allegation, first made in the written Restriction Requirement, that the various Groups are patentably distinct because they have "acquired a separate status in the art as shown by their different classification and a separate subject matter for inventive effort." Applicant respectfully submits that restriction of Group I and claims 65-67, 92 and 93 of Group II, and restriction of Group I and claims 71-73 of Group IV, is improper for the reasons set forth in detail below.

Restriction of Groups I and II (in part)

Inventions that are related as a combination and subcombination are distinct and restriction may be proper **only if** it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

It is first noted that instant claims 65-67, 92 and 93, placed in Group II, are not directed to kits, but rather are directed to combinations of the pharmaceutical compositions of Group I and a vial. In this instance, if the compositions of Group I are deemed free of the prior art, the combinations of

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claims 65-67, 92 and 93 of Group II, which contain the compositions of Group I, will necessarily be free of the prior art. Therefore, the combinations of claims 65-67, 92 and 93 of Group II and compositions of Groups I are not distinct.

If the claims are restricted into these two groups, applicant ultimately could be granted two patents, one that includes claims encompassing pharmaceutical compositions, and another with claims directed to combinations containing the compositions, that expire on different dates. If the claims to the combinations (combinations containing a composition and a vial) issued first, a later issuing patent encompassing the subcombination (compositions) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, which states:

[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

The Office Action alleges that Groups I and II are independent and distinct because they allegedly have different classifications. As noted above,

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instant claims 65-67, 92 and 93, placed in Group II, are not directed to kits, but rather are directed to combinations of the pharmaceutical compositions of Group I and a vial. It is respectfully submitted that the combinations of instant claims 65-67, 92 and 93 have not been properly classified. Since restriction of Group I and claims 65-67, 92 and 93 of Group II is improper, reconsideration and withdrawal of the restriction requirement as between Group I and claims 65-67, 92 and 93 of Group II is, therefore, respectfully requested.

Restriction of Groups I and IV

As noted above, inventions that are related as a combination and subcombination are distinct and restriction may be proper **only** if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

In this instance, if the compositions of Group I are deemed free of the prior art, the articles of manufacture of claims 71-73 of Group IV, which contain the compositions, will necessarily be free of the prior art. Therefore, the articles of manufacture of claims 71-73 of Group IV and compositions of Group I are not distinct.

If the claims are restricted into these two groups, applicant ultimately could be granted two patents, one that includes claims encompassing pharmaceutical compositions, and another with claims directed to articles of manufacture containing the compositions, that expire on different dates. If the claims to the combinations (articles of manufacture) issued first, a later issuing patent encompassing the subcombination (compositions) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, *supra*. See, also MPEP 804.01, *supra*.

As noted above, if the pharmaceutical compositions of Group I are deemed free of the prior art, then the articles of manufacture of claims 71-73 of Group IV, which contain the pharmaceutical compositions of Group I, will

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necessarily be free of the prior art. Since restriction of such Groups is improper, reconsideration and withdrawal of the restriction requirement as between Group I and claims 71-73 of Group IV is, therefore, respectfully requested.

* * *

In view of the above, Applicant hereby petitions for reconsideration and removal of the Restriction Requirement as between Group I and claims 65-67, 92 and 93 of Group II, and as between Group I and claims 71-73 of Group IV. Since Applicant has elected Group I, with traverse, in the instant application, it is respectfully requested that Group I, claims 65-67, 92 and 93 of Group II, and claims 71-73 of Group IV, be combined for examination herein.

Respectfully submitted,
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